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September 4, 1998

Dockets Management Branch
Attn: (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: DOCKET 98N-0339, Comments on Implementation of FDAMA Center for Biologics Evaluation and Research, August 14, 1998 Public Meeting

Dear Colleagues:

As a representative of the regulated industry, I was asked to attend the above public meeting and comment on how FDA can best meet its Section 406(b) objectives. The format for the comments that follow adheres to the six questions addressed during the public meeting.

1. *"Are there objectives or issues related to the Agency's statutory obligations other than the six objectives identified in FDAMA?"*

Comments:

The paramount issue articulated by Dr. Alan Goldhammer, BIO, during his presentation at the August 14, 1998 meeting is FDA's need for adequate resources. PDUFA narrowly met that need for user-fee products and has provided a management process for non-user fee products. This well-organized process is incapable of accommodating the increase in workload, complex technologies and diminishing resources for the non-user fee products. As stated by Dr. Goldhammer, the regulated industry giving money to FDA through PDUFA doesn't solve all the problems. "FDA must present its budgetary needs to both the Office of Management and Budget and the Congress in a realistic and forceful manner."

The regulated industry needs to step up and provide FDA with the persuasive demonstration of need and work in partnership with FDA during the budgetary process to ensure that Congress understands it's not just FDA, but also its constituency that is asking for funding.

2. *"What should FDA do to adequately meet the demands that are beginning to pressure the application review process?"*

These comments primarily address non-user fee products.
Comments:

A. Consider a joint Industry/FDA initiative to identify accredited third-party review organizations. It needs to cover all application types: IND, BLA, PMA and 510(k)s. Limiting its use only to 510(k)s as we have seen in the CDRH pilot will not stimulate participation because the complex submission types have the most impact to industry turnaround time needs and FDA resource capabilities.

B. Implement section 119 of FDAMA - meetings and performance goals. These procedural requirements will make the product development, review and approval process more predictable. The establishment of guidance for and adherence to predetermination and binding clinical trial agreements will resolve issues in a timely manner and maintain consistency in the submission review process.

The review process today is difficult for the sponsor because it takes 12 months to obtain a review letter that may require long-term studies. More timely reviewer feedback on a monthly basis, although understood to be draft comments, would significantly benefit industry if additional public health issues necessitate more information during the review process.

More work is needed to refine the "changes to be reported" guidance for manufacturing changes. The current guidance does not adequately balance the potential effects to safety and efficacy with the refinements in Quality System regulation. Not enough consideration is given to whether changes are sufficiently assessed and controlled through the QSR field inspection process as opposed to reporting changes via 21CFR 601.12.

3. *"How can FDA work with its partners to ensure that products produced and marketed by regulated industry are of high quality and provide necessary consumer protection?"*

Comments:

Efforts should continue in the global arena in assessing experience gained from the use of third-party assessors (notified bodies) and adverse event reporting. Electronic capture and analysis should provide added assurance of timely monitoring and response to public health concerns.

4. *"How can FDA best establish and sustain effective, timely and review-based postmarketing surveillance system for reporting injuries associated with all FDA regulated products?'"*

Comments:
Establishing an electronic metrics-based quality system for capturing, analyzing and reporting of postmarket surveillance data could provide trend information for corrective action decisions as stated in #3 above. This information together with inspectional observation and recall profiles would add to the vendor selection process of important product components and services.

5. *"What approach should FDA use to ensure that it has continued access to the scientific expertise needed to meet its statutory obligations and strengthen its science-based decision-making process?"*

Comments:

Joint FDA and industry working groups to help establish scientific consortiums of opinion leaders would provide continued access to scientific expertise seminars on breakthrough and innovative technology.

6. *"How can FDA best maximize its outreach efforts to ensure the availability and clarity of information about new products...and about the process for review of applications and submissions.....related to the Agency's statutory regulations?"*

Comments:

The current agency tools, i.e., Internet use, fax-on-demand and public meetings are effective. Resources appear to be lacking to maintain indexes that are updated in a timely manner that provide "efficient" retrieval of appropriate information that is current.

Sincerely,

ABBOTT LABORATORIES

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Director, ADD Regulatory Affairs

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